GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:2891
ANSWERED ON:17.12.2008
SPURIOUS DRUGS
Nedurumalli Janardhana Reddy Shri ;Rao Shri Kavuru Samba Siva

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the details of the findings of the Indian pharma industry and Organization for Economic Co-operation and Development and the Government's assessment on counterfeit and spurious drugs affecting adversely the health of patients in the country;

(b) the steps taken by the Government in this regard;

(c) whether the Government proposes to establish a drug regulator to ensure sale of genuine drugs in the market;and

(d) if so,the details thereof?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE(SMT. PANABAKA LAKSHMI)

(a) No scientific survey report is available on the extent of spurious drugs in the country.The ASSOCHAM had reported a very high percentage of spurious drugs in the country which was not realistic and based on the declining market share of the original manufacturers of drugs.Infact, a study of sample of drugs tested all over the country in last five years reveals that only about 0.3% to 0.4% of around 40000 samples per annum fall within the category of spurious drugs.The report of Organization of Economic Cooperation and Development (OECD), an international organization concerning economic cost of counterfeiting and piracy, recommends increased enforcement of existing laws and tighter cooperation between governments and industry to make policies more effective.

(b) The following steps have been taken by the Government to check the menace of spurious drugs:

1. Parliament has recently enacted amendments in the Drugs and Cosmetics Act, 1940 providing for more stringent penalties for those indulging in malpractices relating to spurious drugs by passing the Drugs and Cosmetics (Amendment) Bill,2005.

2. The Central Government has undertaken a survey to assess the extent of spurious drugs in the country based on the study designed by the Indian Statistical Institute, Hyderabad.Around 31000 samples collected from different zones from the five strata i.e. Metro cities, big cities,towns, districts HQ, villages will be analyzed to assess the availability of spurious drugs.

3. Specific training program for regulatory officials of State Governments on logistics of intelligence work,prosecutions,etc. has been conducted with the assistance of FDA,Maharashtra.

4. Pharma industry and trade has been motivated to fight menace of spurious drugs as a shared responsibility.Initiative taken by Pharma industry through their network would help in detecting and investigating more number of cases successfully.

(c) & (d) The Central Drugs Standards Control Organization (CDSCO) under the Central Government and the concerned agencies of the State Governments are already attending to this aspect.However, a Bill namely the Drugs and Cosmetics (Amendment) Bill,2007 has been introduced in Rajya Sabha on 21.08.2007 providing for inter-alia creation of a Central Drug Authority.